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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MIGUELANGELO J. PEREZ-CRUET[1]

Appeal 2016-006252
Application 13/793,635
Technology Center 1600

Before JEFFREY N. FREDMAN, RICHARD J. SMITH,
and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to methods for treating cancer, which have been rejected as indefinite, for failing to satisfy the written description and enablement requirements, and as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

STATEMENT OF THE CASE

One characteristic of all types of tumor cells is that they proliferate through neovascularization. Spec. ¶ 4. "Neovascularization is a process of

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[1] Appellant identifies the Real Party in Interest as MI4Spine, LLC. Appeal Br. 3.

tissue vascularization that involves the growth of new blood vessels into a tissue. Tissue cells utilize blood vessels to supply oxygen and nutrients, and to remove waste products. Neovascularization of tumor cells plays a critical role in the development and progression of cancer." Spec. ¶ 5. The present invention involves a method to inhibit neovascularization by surrounding the tumor cells with a barrier comprising chondrocytes. Spec. ¶ 6.

Claims 1–4, 8, 9, 11–14 and 16–22 are on appeal. Claim 1 is representative of the rejected claims and reads as follows:

> 1. A method for administering a barrier cell treatment for tumors, said method comprising:
>
> identifying a location of tumor cells in a body part;
>
> preparing a tumor treatment material that includes chondrocytes; and
>
> administering the tumor treatment material to a location in the body part around the tumor cells so that the tumor cells are surrounded by the tumor treatment material so as to create a chondrocyte barrier around the tumor cells that operates to prevent or reduce tumor cell growth.

The claims stand rejected as follows.

Claim 9 has been rejected under 35 U.S.C. § 112, second paragraph, as indefinite.

Claims 1–4, 8, 9, 11–14 and 16–22 have been rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement.

Claims 1–4, 8, 9, 11–14 and 16–22 have been rejected under 35 U.S.C. § 112, first paragraph, as non-enabled.

Claims 1, 4, 8, 9, 11, 14, 16, 17, 19, and 21 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Binette.[2]

Claims 1, 4, 8, 9, 11–14, 16, 17, and 19–22 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Binette in view of Palasis.[3]

Claims 1–4, 8, 9, 11, 14, 16–19, and 21 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Binette in view of Warner.[4]

INDEFINITENESS

Issue

The issue with respect to this rejection is whether a preponderance of evidence supports the Examiner's finding that claim 9 is indefinite.

The Examiner finds the term "using stem cell differentiated chondrocytes" is indefinite in that it is not clear if the chondrocytes are derived from previously differentiated stem cells or if the method incudes the step of differentiating stem cells. *Id.*

Appellant contends that one skilled in the art would understand that the claim refers to obtaining chondrocytes from stem cells. Appeal Br. 9.

We find that the Examiner has the better positon. As the Examiner has explained, it is unclear what is meant by the term "using stem cell differentiated chondrocytes." Ans. 24. The term "using" is unclear as it relates to the phrase "using stem cell differentiated chondrocytes". *Id.* As

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[2] Binette et al., US 2005/0054595 A1, published Mar. 10, 2005 ("Binette").
[3] Palasis, US 6,689,103 B1, issued Feb. 10, 2004 ("Palasis").
[4] Warner and O'Dorisio, *Radiolabled Peptides in Diagnosis and Tumor Imaging Clinical Overview,* Vol. 32-2 SEM. NUCL. MED. 79 (Apr. 2002) ("Warner").

the Examiner points out, the phrase can be interpreted more than one way. *Id.* For example, the claim can be read to mean that the stem cell derived chondrocytes are added to the tumor treatment material, that a step of differentiation of chondrocytes is required, or that the use of such cells is another step in the method claim. When a claim term is subject to different reasonable interpretations, the claim is indefinite. *Ex parte Miyazaki*, 2008 WL 5105055, at *5 (BPAI 2008) (precedential).

Conclusion of Law

We conclude that a preponderance of the evidence supports the Examiner's conclusion that claim 9 is indefinite.

WRITTEN DESCRIPTION

Issue

The issue with respect to this rejection is whether a preponderance of the evidence supports the Examiner's conclusion that the written description requirement has not been met.

The Examiner finds that the Specification fails to describe how the claimed barrier is created. Final Act. 10–12. The Examiner finds that the Specification does not provide any information as to how the injected chondrocytes come together to form a barrier. Final Act. 10. The Examiner also finds that the physical properties of the administration steps, such as the quantity of chondrocytes to be administered are not disclosed. *Id.* The Examiner goes on to find that the Specification fails to describe the structure required to effectively act as a barrier. *Id.* The Examiner finds that the Specification only teaches one proposed method to administer the

chondrocytes. Final Act. 12. Based on these findings the Examiner concludes that the written description requirement has not been met. Final Act. 12–13.

Appellant contends that the Specification, particularly Figure 4 and the accompanying discussion, adequately describes the invention. Appeal Br. 12. Appellant also contends that there is no requirement that more than one way to practice the invention must be disclosed.

Principles of Law

A description adequate to satisfy 35 U.S.C. § 112, first paragraph, "must 'clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.' In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (citation omitted, alteration in original).

"One needs to show that one has truly invented the genus, i.e., that one has conceived and described sufficient representative species encompassing the breadth of the genus. Otherwise, one has only a research plan, leaving it to others to explore the unknown contours of the claimed genus." *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1300 (Fed. Cir. 2014).

Analysis

We agree with the Examiner that the instant claims fail to satisfy the written description requirement in that the Specification does not convey to one skilled in the art what Appellant has invented. Ans. 25. Appellant's disclosure appears to be little more than a gedanken experiment with almost no details as to how the barrier is formed or what properties are needed to create an effective barrier. At best, Appellant has presented a research outline for others to follow which is insufficient to satisfy the written description requirement. *AbbVie* , 759 F.3d at 1300.

We have considered Appellant's argument regarding Figure 4 and the accompanying text and find it unpersuasive. Appeal Br. 12. While the Figure shows administration of chondrocytes, as the Examiner points out, the Specification is devoid of any disclosure as to how the barrier is achieved. Ans. 25. There is nothing in the Specification to show how many chondrocyte are needed to form a barrier or how the individual chondrocytes are induced to form a barrier.

Conclusion

We conclude that a preponderance of evidence supports the Examiner's conclusion that the claims fail to comply with the written description requirement.

ENABLEMENT

Issue

The issue with respect to this rejection is whether substantial evidence support the Examiner's conclusion that the claims fail to satisfy the enablement requirement.

Applying the factors recited in *In re Wands,* 858 F2d. 731 (Fed. Cir. 1988), the Examiner finds that

1) The Specification only teaches injection of the chondrocytes whereas Appellant arguments imply that the method requires something more than mere injection;
2) The art is unpredictable;
3) The level of skill in the art is high;
4) The amount of guidance in the specification is limited and there are no working examples;
5) The amount of experimentation is undue given the state of the art and the lack of guidance in the Specification. Final Act. 13–16.

The Examiner concludes that one skilled in the art could not practice the claimed invention without engaging in undue experimentation. Final Act. 16.

Appellant contends that the steps for performing the invention are well known in the art. Appeal Br. 14. Appellant contends that undue experimentation would not be required to practice the invention. *Id.*

Principles of Law

"Section 112 requires that the patent specification enable those skilled in the art to make and use the full scope of the claimed invention without

undue experimentation. . . . [*S*]*ee also In re Goodman*, 11 F.3d 1046, 1050 (Fed. Cir. 1993) ('[T]he specification must teach those of skill in the art how to make and how to use the invention as broadly as it is claimed.')."

Invitrogen Corp. v. Clontech Labs. Inc., 429 F.3d 1052, 1070–71 (Fed. Cir. 2005) (internal quotes omitted).

> [A] specification need not disclose what is well known in the art. However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. . . . It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.

Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997) (citation omitted).

> When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. If the PTO meets this burden, the burden then shifts to the applicant to provide suitable proofs indicating that the specification is indeed enabling.

In re Wright, 999 F.2d 1557, 1561–62 (Fed. Cir. 1993).

"Attorneys' argument is no substitute for evidence." *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1581 (Fed. Cir. 1989).

Analysis

Once again, we conclude that the Examiner has the better position. As discussed above with respect to the written description requirement, Appellant has only described a concept without any meaningful disclosure as to how to accomplish it. There is nothing in the Specification to teach one skilled in the art how the chondrocyte barrier is formed.

Appellant's argument that one skilled in the art would know how to perform each of the steps is unpersuasive. Appellant offers only attorney argument that the performance of each step is known in the art. "Attorneys' argument is no substitute for evidence." *Johnston*, 885 F.2d at 1581. Moreover, the Specification does not teach how the chondrocytes actually form the required barrier nor has Appellant asserted that this was known to one skilled in the art. *See, e.g.,* Appeal Br. 4.

Conclusion of Law

We conclude that substantial evidence supports the Examiner's conclusion that the claims are not enabled.

OBVIOUSNESS

Each of the rejections under 35 U.S.C. § 103(a) are based on the Binette references and Appellant's arguments focus on the teachings of Binette. Appeal Br. 16–17. Thus, the issue with respect to the rejected claims is whether a preponderance of the evidence supports the Examiner's

conclusion that the claims would have been obvious over Binette, either alone or in combination with Palasis or Warner.[5]

Central to the arguments made by Appellant, and the Examiner's position, is the interpretation of the term "administering the tumor treatment material to a location in the body part around the tumor cells." The Examiner has interpreted the term to include "administration of the material in any location close to the tumor cells including inside the tumor." Ans. 29–30. Appellant contends that the term should be read to mean that the tumor treatment material is outside the tumor. Reply Br. 3.

We find that the Examiner's interpretation is correct. "[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification." *In re Hyatt,* 211 F.3d 1367, 1372 (Fed. Cir. 2000). The term "administration of the tumor treatment materials in the body part around the tumor cells" is properly interpreted to include injecting the chondrocyte into the tumor. Injecting the cells into the tumor will still result in chondrocytes "around" one or more of the tumor cells, even though the entire tumor may not be surrounded.

Appellant's argument is not persuasive. The claim term is "around the tumor *cells*" not the tumor. Thus, a method which results in the chondrocyte material surrounding one or more of the tumor cells is within the scope of the claims.

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[5] While Appellant argues the rejections based on Binette combined with Palasis and Warner separately, Appellant's arguments only state that neither Palasis nor Warner "provide the teaching missing from Binette." Appeal Br. 17–18.

Turning to the Binette reference, Binette teaches injecting chondrocytes into a tumor, resulting in reduction of the tumor. Binette ¶¶ 1, 8, 9, and 94. While Binette does not expressly teach the formation of a barrier, as the Examiner has noted, the steps of Binette and the present invention are the same. Ans. 32. Appellant has offered no evidence to show that the claimed invention would perform differently from the method disclosed in Binette. *See In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) ("Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.")

Appellant argues that Binette is directed to injecting the chondrocytes into a tumor whereas the present invention is directed to placing the chondrocytes around the exterior of the tumor. Appeal Br. 17, Reply Br. 2–3. We are unpersuaded. As discussed above, the claims refer to placing the material around the tumor cells, not the tumor as a whole. Thus, the claims embrace injecting the material into the tumor such that it surrounds one or more cells.

We conclude that substantial evidence supports the Examiner's conclusion that the rejected claims would have been obvious over Binette alone or in combination with either Palasis or Warner under 35 U.S.C. § 103(a).

SUMMARY

We affirm the rejection under 35 U.S.C. § 112, second paragraph.

We affirm the rejections under 35 U.S.C. § 112, first paragraph.

We affirm the rejections under 35 U.S.C. § 103(a).

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED